UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: GADOLINIUM-BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION	)	**Case No. 1:08 GD 50000**
	)	**MDL No. 1909**
	)	**Judge Dan Aaron Polster**
Paul Decker, et al.,	)	**Case No. 1:12 GD 50004**
- against -	)	**MEMORANDUM OF OPINION AND ORDER**
GE Healthcare, Inc., et al.,	)	

The Court has reviewed Defendants' Objection to Preliminary Jury Charge (Doc. # 179) and Plaintiffs' response thereto (Doc. # 180). The instruction to which Defendants object, "Compliance with Regulations," currently reads as follows:

> You have heard evidence in this case that the Food and Drug Administration (or "FDA") approved Omniscan as "safe and effective" for its intended uses, that the FDA approved Omniscan's label or "package insert" in place at the time of Mr. Decker's Omniscan administration, and that the FDA required changes to the label in 2007 and 2010, after the time of Mr. Decker's Omniscan administration. While FDA approval may be evidence of reasonable care, it is not conclusive proof of reasonable care. Consider this evidence along with all the other evidence when you decide if Defendants used reasonable care.
>
> Furthermore, if Defendants became aware of facts tending to show that Omniscan was unsafe for certain purposes or required stronger warnings after FDA approval, Defendants were obligated to provide those additional warnings and did not need FDA approval before doing so.

After reviewing the parties' briefs, the instruction, and the relevant law, the Court finds that the first paragraph is correct and clear. The second paragraph, however, tends to oversimplify the manufacturer's duty to warn, which was never the Court's intention. Accordingly, the second paragraph will be revised to read as follows to accurately capture the rule articulated in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009):

> Furthermore, a drug manufacturer bears the ultimate responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. The manufacturer does not need approval from the FDA before strengthening its warnings.

This revision will be incorporated into the Preliminary Jury Charge and the Final Jury Instructions, copies of which the Court will email to counsel.

IT IS SO ORDERED.

/s/ Dan A. Polster March 4, 2013
Dan Aaron Polster
United States District Judge